

2008/SOM1/SCSC1/TFTF/002

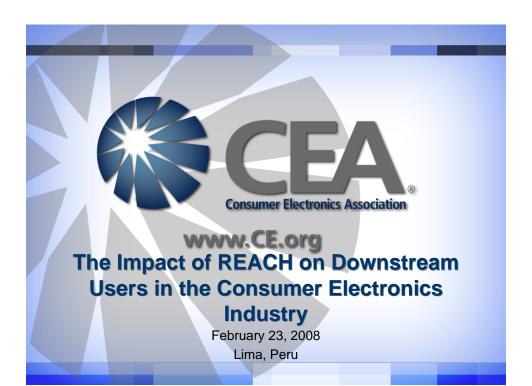
Agenda Item: 4

The Impact of REACH on Downstream Users in the Consumer Electronics Industry

Purpose: Information
Submitted by: Consumer Electronics Association (CEA)



Sub-Committee on Standards and Conformance Trade Facilitation Task Force Meeting Lima, Peru 23 February 2008



CEA Overview

- More than 2,200 members engaged in the development, manufacturing and distribution of all consumer electronics, communications and multimedia products and services that are sold via global consumer channels
- While CEA is a U.S.-based association, our members are global
 - Global supply chain
 - Global R&D
 - Significant consumer base in Europe and Asia



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REACH Myths vs. Realities

MYTHS

- REACH is only a chemical industry issue
- REACH is an EU-based company problem
- Downstream users do not have to prepare

REALITIES

- REACH poses business risk to any company doing business in the EU, not simply to chemical companies
- With a globalized supply chain, there is no such thing as a domestic problem – the *entire* supply chain will be affected by REACH
- All companies that make use of chemicals in their components or in the final product must develop strategic action plans in order to manage REACH



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CEA Outreach Trip to Brussels November 2007

- DG Enterprise shared that much of REACH legislation is finalized, although there are still some remaining issues regarding IP
- CEA discussed high fees and concern that SMEs would have difficulty managing administrative burden
- In the Fall of 2008 there will be an opportunity for comment on substances considered by the Commission to be of "very high concern"



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Status of CE Industry REACH Preparation

- Still trying to understand requirements ahead of pre-registration date
- Focused on cost, administrative burden and necessary supply chain changes
- Much uncertainly remains; more engagement needed
- Many webinars, conferences, presentations, resources



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What is a Downstream User?

- Any individual that uses a substance during the industrial phase of production.
- A downstream user may manufacture the preparations themselves or articles that use preparations (which is the case in the consumer electronics industry)
- Also includes re-importers of substances
- Excludes distributors and consumers



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General Obligations of Downstream User

- Conduct inventory on all substances, preparations in articles that are manufactured, imported (by U.S. company to EU affiliate) or purchased – Chemical Safety Assessment (CSA)
 - ** Each EU affiliate may be a separate legal entity
- Dictate exposure scenario for all uses and must recommend measures to "adequately control the risks"
- Perform "hazard assessment" on all substances (effect on human health and the environment)



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General Obligations: Content of Inventory

- Substance identification
- Tonnage
- Whether produced, imported, used, etc.
- REACH exemptions
- Classification
- Suppliers
- Customers/Applications and uses
- Contracts
- SVHCs (Authorization, Restrictions)
- Other important information (data requirements, etc.)



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General Obligations of Downstream Users

- Register all substances contained in component or final product (1 ton threshold per manufacturer) with European Chemicals Agency (ECHA)
 - Can divide weights among all importers if manufacturer has multiple importers in EU.

SUPPLY CHAIN

- Ensure input providers are REACH compliant
- Develop maintenance program to ensure adjustments to design and manufacturing process are consistently in compliance starting with preregistration period
- Closely monitor exemptions process



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General Obligations of Downstream Users (cont.)

- If substances included in product are PBT, vPvB or are classified as "dangerous" according to EU law, then company must perform exposure and risk assessments
- Manufacturers/Importers registering the same substance at the same time (within the same tonnage band) must register jointly



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How do Downstream Users Make REACH Easier to Manage?

- 1. Form Consortia in order to reduce registration costs
 - Share test costs
 - Benefit from reduced registration fees
 - Share administrative burden



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How do Downstream Users Make REACH Easier to Manage?

- 2. Appoint an "Only Representative"
 - Must be non-EU
 - Takes on registration and other REACH responsibilities for manufacturers
 - Must have "sufficient background in the practical handling of substances and the information related to them"
 - Must maintain current information on quantities and customers





Only Representative – Other Issues

- When imports are covered by an only representative, importers are considered downstream users:
 - They must assess information received
 - They must assess risk management measures
 - They may need to recommend risk management measures further down the supply chain



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Challenge: Defining Substances in Articles

- Substances intended to be released under normal or reasonably foreseeable conditions of use must be registered if above 1 tonne per year
- Substances contained in articles above 0.1% w/w must be **notified** if they are included in candidate list and if above 1 tonne per year



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Challenge: Defining Substances in Articles (cont.)

- How do you define an "article"
- How do you define "intentional release"
- Information must be provided within 45 days of receipt of request
- Enforcement still a bit of a mystery



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More Downstream User Obligations

- Must let supplier know how substance will be used so supplier can include "use" in registration
- Information on use of substance and/or preparation must be maintained through the supply chain
- Identify, apply and, where suitable, recommend appropriate risk reduction measures



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Uncertainties

- EU will be adding new substances of high concern to already existing regulations – where does it stop?
 - Process was supposed to begin in January 2008 –
 has not happened
- Fees
 - Potentially high for SMEs (depending on tonnage)
 - EUR 2500 just to notify Agency of change in legal entity
 - Additional regulatory fees?



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Fee Proposal

Response from European Chemicals Agency (ECHA)

- Proposal reflects principles set by Council and Parliament in the REACH Regulation, specifically that the level of fees must take into account the workload involved
- Level of fees and charges foreseen expected to cover about 2/3 of the Agency's costs related to implementation of REACH; remaining costs covered by a Community subsidy
- Very significant reductions (up to 90%) have been foreseen for the smallest companies with a view to facilitate their compliance
- REACH committee gave favorable opinion on the Commission's draft on 10 December 2007. Thus, ECHA expects adoption of Regulation well in advance of 1 June 2008.



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More Uncertainties

- Only Representative
 - Liability issue?
- Public access to substance information
 - Competition/IPR Infringement?
- Educating suppliers outside of EU on **REACH** requirements
- Lack of final REACH guidance by EU



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Contact Information

Parker Brugge Senior Director and Environmental Counsel Consumer Electronics Association 1919 S. Eads Street Arlington, VA 22202 (703) 907-7765

pbrugge@ce.org



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